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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/487,359	01/19/2000	Dean A. Schaefer	1001.1387101	3074

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/487,359

Applicant(s)

SCHAEFER ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6, 11, 13-15, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S Patent No. 5057092 to Webster Jr.

Webster discloses a braided catheter with low modulus warp. Referring to FIG 2 this apparatus contains an inner tube 22 and outer tube 30 and an interwoven helical reinforcement layer 24 with an axial member 28. The reinforcement layer is located between the outer tube 30 and the inner tube 22. The inner and outer surfaces are free of protrusions caused by axial member 28.

The inner and outer walls 22 and 30 are made of flexible plastic material such as polyurethane. (Col.2, line 33) The axial member is made out of material with a level of flexibility, in which it allows for movement in relation to inner and outer tube. The helical members 24 are made of material having a high modulus of elasticity. Preferred helical members are made of stainless steel wire, although, depending on the application material such as Kevlar thread and modified polyethylene material may be used. (Col.2, lines 55-65)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5,7-8, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr. as applied to claim 1 above, and further in view of U.S Patent No. 5891191 to Stinson.

As mentioned above Webster discloses a braided catheter with low modulus warp. Webster, however, does not disclose the possibility of the helical members comprising of monofilaments. Stinson discloses a cobalt-chromium-molybdenum alloy stent and stent graft. Stinson's stent is made out of interwoven helical bridges, which are made of monofilaments.

Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to combine the two studies because according to Stinson monofilaments are highly resilient, and allow deformation under external stress, but elastically return to the nominal shape when free of the external stress. (Col. 8, lines 35-38) This quality is highly desirable because when placing an object in to the vessel one can be assured that this apparatus is resilient to precede in the procedure yet is flexible enough not to treat through organs.

3. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr. as applied to claim 1 above, and further in view of US Patent No. 5749891 to Ken et al.

As mentioned above Webster discloses a braided catheter with low modulus warp. Webster, however, does not teach the helical material comprising of radiopaque

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material. Ken discloses a multiple layered vaso-occlusive coils. Ken teaches the coils that make up the stent may be made of radiolucent fibers or polymers.

Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to combine the two studies because to place a helical member coated with radiopaque will allow the caregiver to follow the procedure with series of X-Rays, it gives the physician eyes inside the patients lumens. With any procedure in medicine being able to see which part of the body you are advancing up on is half the battle, if you don't have visualization it will increase the risk of injure to the patient 10 fold.

4. Claims 9-10, 19-21, 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr, and further in view of US Patent No. 6361637 to Martin et al.

As mentioned above Webster teaches the invention except for utilizing monofilament comprising of liquid crystal polymers in a flat ribbon. Martine teaches a stent made form monofilaments comprising of liquid crystal polymers in a flat ribbon.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have added Martin's monofilament comprising of liquid crystal polymers in a flat ribbon to Webster's invention, because according to Martine the ribbon formation allows kink resistant for the stent and the liquid crystal polymers add to the physical torsion enhancing ability of the stent. (Col.11, lines 50-65)

Allowable Subject Matter

5. The indicated allowability of claims 9-10 and 19-21 are withdrawn in view of the newly discovered reference(s) to US Patent No.6361637 to Martin et al. Rejections based on the newly cited reference(s) follow.

Response to Arguments

6. Applicant's arguments filed 9-27-2002 have been fully considered but they are not persuasive.

a. In response to applicant's argument that claim one over comes the recited prior art due to the recited amendment which reads "wherein the axial member limits elongation of the catheter under tension but does not substantially reduce catheter flexibility", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

b. Applicant further argues that the examiner has no motive to combine Stinson with Webster. As the examiner has recited above Stinson monofilaments are highly resilient, and allow deformation under external stress, but elastically return to the nominal shape when free of he external stress. (Col.

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8, lines 35-38) This quality is highly desirable because when placing an object in to the vessel one can be assured that this apparatus is resilient to precede in the procedure yet is flexible enough not to treat through organs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



RG
November 22, 2002



MICHAEL J. HAYES
PRIMARY EXAMINER